K051073

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Exhibit E 510(k) SUMMARY - The Millennium Devices MDI-VIEW Series of Endoscopes and Accessories

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification**

MAY 17

Submitter's Name:	Millennium Devices Inc.
Address:	250 Gibbs Road, Islandia, NY 11749
Telephone Number:	631 582 8440
Contact Person:	Dr. Joseph Librizzi, President
Date Prepared:	

2. **Name of Device**

Proprietary Name:	MidiView Series of Microendoscopes
Common/Usual Name:	Micro Endoscopes and Accessories
Classification Name:	Endoscopes, Rigid
Classification:	CGM, CGQ and KYH

3. **Predicate Device Information**

The FDA has cleared dozens of predicate devices with design theory and specifications very close to if not exactly the same as the Millennium Devices MDI-View MicroFibreEndoscope series of endoscopes and accessories. A small cross section of predicates is included in this submission for review.

DOFI Communications Inc. Miniature Endo/Laparoscope and accessories, (K983527)
Acueity In.c. ViaDuct Micro endoscope and Accessories (K011189)
Karl Storz Inc. Sialoendoscope and accessories (K012527)
Davlite Technologies Davlite Micro Endoscope and Accessories (K020310).
Akermann Instrumente Laparoscopes and Accessories (K974382)

4. **Device Description**

The Millennium Devices Inc. MDI-View MicroFibre Endoscope Series and Accessories are fiber optic based flexible and semi rigid endoscopes intended to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs and canals. They also provide working channels to allow insertion of tools and accessories such as drills and stone baskets to facilitate therapeutic procedures. All scopes incorporate an irrigation channel that may provide irrigant flow to the distal end for flushing the operative site.

All of the endoscopes are semi rigid, except the SinoView scopes which are flexible. All incorporate a 0.35 mm diameter, 6000 pixel fiber bundle. The SinoView scope is flexible. Surrounding this bundle are fibre cables that are used as light guides. Standard glass lens oculars are provided. Stainless steel sheaths are used for the endoscopes. Each scope may be attached to standard Fibre Optic light sources and cameras such as the Olympus CLV-160 light source and the Karl Storz Xenon 300 light source. They may also be connected to CCD video adapters that in turn may be used to project the image on standard medical grade TV monitors.

All models also include working channels that may be used to introduce accessories such as biopsy needles, stone baskets, drills or other standard type tools. These tools allow the endoscopes to be used in therapy as well as diagnosis of disease.

5 **Intended Use:** used to examine body cavities, hollow organs and canals, and, using additional accessories, to perform various diagnostic and therapeutic procedures in the following surgical specialties

Plastic and Reconstructive Surgery
General Surgery
Ear, Nose and Throat Surgery
Various diagnostic and therapeutic procedures including but not limited to the diagnosis and treatment of salivary gland diseases.
Ophthalmic Surgery
Various diagnostic and therapeutic procedures including but not limited to lacrimal duct visualization and obstruction removal.
Urology
Gastroenterology
Endocrinology
Orthopedic Surgery
Various diagnostic and therapeutic procedures including but not limited to the arthroscopic diagnosis and treatment of joint diseases.

6. **Comparison to Predicate Device**

The probe assembly of all of the predicate devices mentioned, such as DOFI Communications Inc. Miniature Endo/Laparoscope and accessories, (K983527) Acueity In.c. ViaDuct Micro endoscope and Accessories (K011189) Karl Storz Inc. Sialoendoscope and accessories (K012527), Davlite Technologies Davlite Micro Endoscope and Accessories (K020310), Akermann Instrumente Laparoscopes and Accessories (K974382) as well as all of the MDI Microendoscopes consists of a fiber optic core. All of the fibers for all of the predicates and the MDI scopes are manufactured by one of two companies based in Japan. These are Fujikura Inc. and Sumitomo Corp. Therefore, the performance of these elements will be substantially equivalent regardless of scope chosen.

Fiber optic bundles that transports light energy into the operative site surround this core. Each scope has at least one working channel into which a tool or other instrument may be inserted to allow a therapeutic function. A metal sheath of either stainless steel

construction surrounds the probe. The probe is semi rigid that aids in insertion and manipulation. The lens system provides 0° Direction of View (directly ahead). The Field of View in Air is 50 to 60 degrees, in Water, 40 degrees for all scopes but the Sialoview T3, which is 40 degrees. The MidiView Sinoview scope is flexible and can angle the proximal end 70 degrees. All scopes of the MidiView series incorporate an irrigation channel that may provide irrigant flow to the distal end for flushing the operative site. All of the predicates also include an irrigation channel.

The fiber bundles and working channel tubing in all predicates and the MidiView Serie are encased in a flexible sheath of varying lengths. This sheath terminates in an ocular that is 8.5X (in the case of the MDI devices) magnification and allows the surgeon to view the operative site directly.

In addition, a second outlet from the sheath allows the endoscope to be connected to a video converter to provide TV monitor viewing of the operative sight or record the procedure on standard video recorders. This is true of all predicates and MidiView scopes.

All of the accessories sold for the MidiView Series of scopes, such as stone baskets, biopsy needles, drills, etc. are based upon the same engineering principles, materials and theory of operation as the predicate devices. Only size will vary from device to device. This is particularly true when comparing the MidiView devices against those of the Ackermann products covered under K974382, since Ackermann Instrumente is the supplier for these accessories to MidiView Inc.

All of the materials of construction are biocompatible as per the Tripartite Modified Matrix or by actual testing.

7. **Safety and Performance Data**

The Millennium Devices MDI-View series of endoscopes and accessories has been designed to and will be tested to pass the following Voluntary Standards:

UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1-18 Collateral Standard
EN 60601-1-2:2001 Electromagnetic Compatibility
FCC Part 18 EMC Requirements

8. **Software Validation** There is no software associated with this product.

9. **Sterilization Validations** All Micro endoscopes have been or will be validated for an SAL-6 sterility by ETO gas. Validation statements are contained in Exhibit J.

10. **Non-Clinical Tests for Determination of Substantial Equivalence:**

Surface Temperature Tests
Optical Resolution Tests

Material Biocompatibility tests
Electrical Dielectric Strength tests
EMC testing
Sterility Testing

11. Conclusions

Based upon an analysis of the operating characteristic specifications, Output of Engineering Tests, FMEA Analysis and Voluntary Consensus Standard Investigations, Millennium Devices Inc. has concluded that The Millennium Devices MDI-View series of endoscopes and accessories is substantially equivalent to the DOFI Communications Inc. Minature Endo/Laparoscope and accessories, (K983527), the Acueity In.c. ViaDuct Micro endoscope and Accessories (K011189), the Karl Storz KSEA sialoendoscope and accessories (K012527) and the Davlite Technologies Davlite Micro endoscope and accessories (K020310), and Akermann Instrumente Laparoscopes and Accessories (K974382).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Millennium Devices, Inc.
% Joseph Librizzi, PhD
President
250 Gibbs Road
Islandia, New York 11749

Re: K051073
Trade/Device Name: Millennium Devices Inc. Midiview Series of MicroEndoscopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 11, 2006
Received: April 14, 2006

Dear Dr. Librizzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

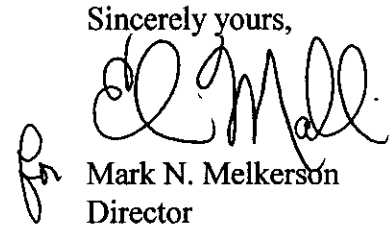
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051073

Indications for Use

510(k) Number (if known): **K051073**
Device Name: **Millennium Devices Inc. Midiview Series of MicroEndoscopes**

Indications For Use: (Continued)

Endoscope Type	Trade Name	Part Number	Indication for Use
Arthroscope	Arthroview	MDI-002000	The Arthroview is intended for use in providing access to and visualization of body cavities, organs and canals to perform various diagnostic and therapeutic surgical procedures
Microendoscopes	Microview Microview T	MDI-003000 MDI-003100	The Microview Series of Microendosocopes are intended for use in providing access to and visualization of body cavities, organs and canals to perform various diagnostic and therapeutic surgical procedures

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051073

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Exhibit C: Indications for Use

510(k) Number (if known): **K051073**
Device Name: **Millennium Devices Inc. Midiview Series of MicroEndoscopes**

Indications For Use:

Endoscope Type	Trade Name	Part Number	Indication for Use
Sialoscope	Sialoview T Sialoview T3 Sialoview	MDI – 004000 MDI – 004100 MDI - 004200	The Sialoview series of microendoscopes are for use by qualified surgeons for the diagnosis and treatment of salivary gland diseases. The Sialoview scopes are used to visualize the surgical site in salivary gland diagnosis and therapeutic procedures.
Nasosinuscope	Sinoview	MDI - 001000	The Sinoview is intended for use in providing access to and visualization of body cavities, organs and canals to perform various diagnostic and therapeutic surgical procedures

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051073